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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,815	12/09/2003	Judi Bryant	52143BUSM1	5738
27586	7590	06/27/2005	EXAMINER	
BERLEX BIOSCIENCES PATENT DEPARTMENT 2600 HILLTOP DRIVE P.O. BOX 4099 RICHMOND, CA 94804-0099			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,815

Applicant(s)

BRYANT ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-23 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/9/03 & 6/7/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Claims 4,7,14,19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1.Claim 4 depends on itself. It appears claim 3 was really intended.
2. Claims 4,7,14,19 and 21 each recite “compound” in the preamble yet what is covered is species in a particular solvent. Thus a composition is actually being claimed not a compound. Thus clarification is needed .

Claims 1-10,12-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Beginning on page 50 through page 56 of the specification preparative examples are described. Numerous of these are **not** obtained in the free form but rather isolated in a solvent mixture after workup such as rotary evaporation or HPLC. The solvent media employed, namely acetic acid, trifluoroacetic acid and trifluoro-ethanediol are not suitable solvents for therapeutic purposes which is the purpose of the invention. Specification is silent as to how these compounds can be further purified **or** if they are only stable in the solution in

which they were obtained. In view of these compounds actually made and particularly claimed in claims 4,7,14,19 and 21, it is reasonable to question the form of recovery for remaining compounds made by the same procedure described herein and if they are “sufficiently robust to survive isolation to a useful degree of purity.....and formulation into an efficacious therapeutic agent” as stated in the specification on p.14.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17,20 and 22-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,59-60 of U.S. Patent No. 6,861,424. Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter at the variable R3 which can be heteroarylalkoxy. US'424

particularly claims R3 as tetrazolylalkoxy and exemplifies species having this group. See species in claim 5 in US'424.

US'424 (and corresponding WO'856) is not a competent reference since it has the same inventive entity as herein.

Claims 1-16 are directed to values of R3 not disclosed/claimed in US'424.


Claims 17-18,20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/947635 (recently allowed). Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter at R3. The copending case is a refiled case of US'424 and it includes subject matter present in US'424 as well as other heteroarylalkoxys including isoxazoles particularly claimed in claim 21 herein. Note that "heterocyclyl" recited in the claims of the copending case is defined to include heteroaryls.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Emily Bernhardt
Primary Examiner
Art Unit 1624